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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,929	06/29/2001	Ki-Seung Choi	EF321688773U	9906

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/30/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,929

Applicant(s)

CHOI ET AL.

Examiner

Lakshmi S Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1615

DETAILED ACTION

Receipt of preliminary amendment B, request for extension of time and request for continued examination on 6-9-03 is acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-9-03 has been entered.

Claims

Claims 2-7 are pending.

Claim 6 recites a biocide composition comprising 3-isothiazolone and polyhexamethyleneguanidine phosphate. Claim 2 recites the ratios of the two compounds of claim 6. Claim 3 recites the ratios of different isothiazolone in the mixture. Claim 5 is a method of killing bacteria, fungi and /or algae by applying the composition of the biocide composition (as in claim 6) New claim 7 is a method of restraining the growth of bacteria, fungi and/or algae by applying the biocide composition (as in claim 6).

Claim Rejections - 35 USC § 103

1. Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 5,278,178 to Hsu and SU 1687261 A1 (hereafter SU '261).

Instant claims are directed to a biocide composition comprising 3-isothiazolone and polyhexamethylene guanidine phosphate and a method of killing or restraining the growth of bacteria.

Hsu teaches synergistic microbicidal and biocidal combination compositions comprising 3-isothiazolone mixtures made up of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one and one or more of other antimicrobial compounds. Hsu teaches that the compositions are useful as commercial biocides for effective and broader control of microorganisms (abstract, col. 2, lines 3-54). Instant specification describes the same compounds taught by Hsu as more preferable isothiazolone compounds (page 6, lines 1-2). Hsu teaches the ratios of isothiazolones as 3:1 (col. 2, lines 56-60), which is within the claimed ratio of 1:20 to 20:1. The other antimicrobial compounds of Hsu are listed in col. 3, lines 1-10. Hsu also teaches additives such as solvents, dispersion agents, surfactants (col.3, lines 30-32), which read on the instant additives for emulsion products (instant claim 4).

Hsu does not teach the instant combination of isothiazolone and polyhexamethylene guanidine phosphate. However, Hsu suggests that a combination of two isothiazolones and other antimicrobial compounds results in a synergy, which affords a more effective and broader control of microorganisms (col. 2, lines 6-15).

SU '261 teaches polyhexamethylene guanidine gluconate as an active component in disinfecting compositions, useful for improving the disinfecting properties of the composition

Art Unit: 1615

(abstract). SU '261 does not teach isothiazolone compounds of the instant invention. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine polyhexamethylene guanidine gluconate of SU '261 with the isothiazolone compounds of Hsu because both the references teach compositions containing antimicrobial compounds for disinfecting or preventing microbial contamination. Therefore, one of an ordinary skill in the art would have expected to achieve a synergistic effect in controlling or preventing microbial growth by combining the two disinfectants.

SU '261 does not teach polyhexamethylene guanidine phosphate and instead teaches gluconate salt of the compound. However, absent any criticality, one of an ordinary skill in the art at the time of the instant invention would have expected the same antimicrobial effect with any salt of polyhexamethylene guanidine i.e., a hydrochloride or gluconate or phosphate salt. With respect to the claimed ratio of isothiazolone and polyhexamethylene guanidine salt, it would have been obvious for one of an ordinary skill in the art to optimize the ratios of different antimicrobial agents in composition containing combination of antimicrobials, such that maximum antimicrobial effect is achieved.

2. Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 5,278,178 to Hsu and SU 1687261 A1 (hereafter SU '261), and further in view of JP 10175809(hereafter JP '809, submitted on PTO-1449).

The teachings of Hsu and SU '261 have been discussed above. Neither teaches a combination of isothiazolone and polyhexamethylene guanidine phosphate. However, Hsu

Art Unit: 1615

suggests that a combination of isothaizolones and other antimicrobials result in a synergistic effect and provide broader control over microorganisms.

JP '809 teaches industrial antimicrobial compositions comprising isothaizolones and polyhexamethylene guanidine hydrochloride and suggests that the synergistic composition is effective against bacteria, fungi, yeast, algae and actinomycetes.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine isothiazolones of Hsu and polyhexamethylene guanidine gluconate of SU '261, with an expectation to achieve a synergistic effect in preventing and controlling microbial growth. Further, optimizing the amounts of individual antimicrobial agents in a composition so as to achieve a maximum antimicrobial effect would have been obvious for one of an ordinary skill in the art.

Although JP '809 teaches hydrochloride salt of polyhexamethylene biguanidine and not a phosphate salt, as explained above, absent any criticality one of an ordinary skill in the art at the time of the instant invention would have expected the same antimicrobial effect with any salt of polyhexamethylene guanidine i.e., a hydrochloride or gluconate or phosphate salt.

Response to Arguments

Applicant's arguments filed 6-9-03 have been fully considered but they are not persuasive.

Applicants discussed the above rejection (made previously, paper # 6) in light of the previously filed Declaration under 37 CFR 1.132, final rejection (paper # 10) and the comparative results presented along with the RCE. Applicants state that the new data that

Art Unit: 1615

compares the efficacy of the phosphate salt of PHMG (present invention) with that of gluconate and hydrochloride salts of the prior art. Examiner notes that an executed declaration will follow shortly. Applicants argue that on contrary to examiner's statement that one of an ordinary skill in the art would have expected the same antimicrobial effect with any salt of polyhexamethyleneguanidine i.e., hydrochloride or gluconate or phosphate salt, the present results show that phosphate salt of PHMG surprisingly and unexpectedly inhibited the growth of most of the tested bacterial and fungal species more effectively than did the other salts of PHMG. Further, applicants urge that the data presented support applicant's original date as well as the results presented in the previous declaration, which indicated that the surprisingly greater synergy observed in the absence of isothiazolone would be maintained in the presence of isothiazolone. Applicants' arguments have been considered but not found persuasive. The present data shows higher antimicrobial activity of phosphate salt of PHMG + 3-isothiazolone, over that of a hydrochloride or a gluconate salt in combination of 3-isothiazolone. However, the phosphate salt is shown to be more active than the other salts only against certain bacteria (such as *E.coli*, *K. pneumoniae*, *P.vulgari* & *A. niger* s), but does not show any more activity than the other two salts against other species (*S. typhimurium*, *P.aeruginosa*, *S.aureus*, *R.oryzae*). Further, the results presented in the table only tested the activity of compounds against bacteria and fungi, whereas the method claims recite algae along with bacteria and fungi. Further, the instant "biocide" composition includes not antibacterial and anti-fungal but also anti-protozoal effect. Thus, the combination of claimed compounds exhibit unexpected synergy only against certain microbial species. Furthermore,

Art Unit: 1615

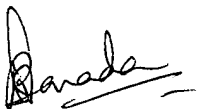
Applicants arguments that Hsu itself negates any expectation of synergism from a combination of antimicrobials are considered but not persuasive because. Hsu does not state whether the compounds (used in combination with their isothiazolone) possess any antimicrobial activity when used alone. In the instant rejections PHMG is known for its antimicrobial activity. Accordingly, the comparison of the examples of Hsu with that of instant not deemed to be proper. Further, as comparative results presented are not in the same scope of the instant claims for at least the anti-algal effect. Furthermore, instant claim 2 recites a specific ratio of the two compounds, whereas the data presented does not state the amounts or the ratios of the compounds. Therefore, the rejection has been maintained.

Art Unit: 1615

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala
Examiner
Art Unit 1615
June 27, 2003